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February 3, 2021

VIA ECF

The Honorable Michael A. Hammer, U.S.M.J.
United States District Court for the District of New Jersey
Martin Luther King Jr. Federal Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *Alkermes, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*
Civil Action No. 20-12470 (MCA)(MAH)

Dear Judge Hammer:

This firm, together with Paul Hastings LLP, represents plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited in the above-captioned matter.

Enclosed is the parties' Joint Proposed Discovery plan for the above matter. We look forward to discussing this and any other issues with Your Honor during the Initial Scheduling Conference for this case on February 5, 2021 at 2:30 p.m.

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,

Charles M. Lizza

Enclosure

cc: All Counsel (via e-mail)

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALKERMES, INC. and ALKERMES PHARMA IRELAND LIMITED, **Plaintiffs,** **v.** **TEVA PHARMACEUTICALS USA, INC. ,** **Defendant.**	**Civil Action No. 20-12470 (MCA)(MAH)** **(Filed Electronically)** **Initial Scheduling Conference: February 5, 2021 at 2:30 p.m.**

JOINT PROPOSED DISCOVERY PLAN

Pursuant to Federal Rules of Civil Procedure 16 and 26(f) and Local Civil Rule 26.1(b), Plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited (collectively, "Alkermes" or "Plaintiffs") and Defendant Teva Pharmaceuticals USA, Inc. ("Teva" or "Defendant") have conferred and submit the following Joint Proposed Discovery Plan.

1. Set forth a factual description of the case. Include the causes of action and affirmative defenses asserted.

This is a "Hatch-Waxman" patent infringement action. Under the 1984 Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"), a generic drug manufacturer may seek approval from the U.S. Food and Drug Administration ("FDA") to market a generic version of an innovator drug by filing an Abbreviated New Drug Application ("ANDA"). Where, as here, the generic manufacturer seeks to market its drug before the expiration of U.S. patents covering the innovator drug, it must certify to the FDA that the innovator's patents are invalid, unenforceable, or will not be infringed. That certification is known as a "Paragraph IV" certification, pursuant to 21 U.S.C. § 355(j) of the Federal Food, Drug, and Cosmetic Act. The filing of an ANDA with a Paragraph IV certification is an act of patent infringement. *See* 35 U.S.C. § 271(e)(2).

Alkermes is an innovator biopharmaceutical company with a focus on developing and marketing products for the treatment of chronic conditions. Alkermes holds NDA No. 021897 and markets VIVITROL® (naltrexone for extended-release injectable suspension) in the United States. Alkermes Pharma Ireland Limited is the owner of U.S. Patent No. 7,919,499 ("the '499 patent"), which is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering VIVITROL®.

Teva manufactures and distributes numerous generic drugs for sale and use throughout the United States. Teva has filed ANDA No. 213195 seeking approval for a generic version of VIVITROL® ("ANDA Product").

Alkermes received a notice letter dated July 29, 2020, sent by Teva, regarding Teva's filing of ANDA No. 213195 with the FDA for a generic VIVITROL® product. The notice letter also stated that ANDA No. 213195 contained a Paragraph IV certification with respect to the '499 patent listed in the Orange Book on that date as covering VIVITROL®.

On September 9, 2020, Alkermes filed a complaint (D.I. 1) against Teva and Teva Pharmaceutical Industries Ltd. for infringement of the '499 patent.[1] Alkermes' complaint contends that Teva's submission of ANDA No. 213195, including its Paragraph IV certification concerning the '499 patent, constitutes patent infringement under 35 U.S.C. § 271(e)(2)(A). Furthermore, Alkermes's complaint asserts that if Teva commercially manufactures, uses, offers to sell, sells, or imports its ANDA Product, or induces or contributes to any such conduct, it would further infringe the '499 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

[1] On October 15, 2020, the Court entered a "Stipulation of Dismissal of Complaint as to Defendant Teva Pharmaceutical Industries Ltd. and Amendment of Caption." (D.I. 11.) Under the terms of this stipulation, Teva Pharmaceutical Industries Ltd. agreed, *inter alia*, to be bound by any Judgment, Order, or decision in this Action, or any appeal thereof.

On November 16, 2020, Teva filed its answer (D.I. 12) to the complaint filed by Alkermes. Teva also asserted one counterclaim against Alkermes, which seeks declaratory judgment that the '499 patent is invalid. Alkermes filed its reply to Teva's counterclaim (D.I. 21) on December 7, 2020.

Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), final FDA approval of Teva's ANDA for its proposed generic version of VIVITROL® is stayed until at least the earlier of the expiration of the 30 month period beginning on the date of receipt by Alkermes of Teva's notice letter (*i.e.*, January 31, 2023) or final resolution of the pending patent infringement lawsuit.

2. Have settlement discussions taken place? Yes ___ No _X_.

3. The parties have _X_ have not ___ exchanged the information required by Fed. R. Civ. P. 26(a)(1). If not, state the reason therefor.

Joint Response: The parties' proposed date for Rule 26(a)(1) disclosures is set forth in the schedule in Exhibit 1.

4. Describe any discovery conducted other than the above disclosures.

Joint Response: On November 16, 2020, pursuant to Local Patent Rule 3.6, Teva produced to Alkermes ANDA No. 213195. On January 26, 2021, Teva produced to Alkermes additional correspondence regarding ANDA No. 213195. Teva represents that, as of this date, there have not been any amendments to this ANDA or additional correspondence regarding the ANDA that would be subject to Local Patent Rule 3.6(j).

5. Generally, dispositive Motions cannot be filed until the completion of discovery. Describe any Motions any party may seek to make prior to the completion of discovery. Include any jurisdictional Motions and Motions to Amend.

Joint Response: The parties do not intend to file dispositive motions before the completion of expert discovery. The parties are not aware of any nondispositive motions at this time but they may seek to file such motions prior to the completion of expert discovery, including, but not limited to, discovery motions or motions to amend in accordance with the attached proposed case schedule in Exhibit 1.

6. The parties proposed the following:

(a) Discovery is needed on the following subjects:

Joint Response: Discovery relating to the claims and defenses in the parties' pleadings, including infringement and validity of the '499 patent, as well as various related issues, claims, and affirmative defenses.

(b) Should discovery be conducted in phases? If so, explain.

Joint Response: Discovery should not be conducted in phases.

(c) Number of Interrogatories by each party to each other party:

Joint Response: Twenty-five interrogatories total per side to be responded to within thirty (30) days of service.

(d) Number of Depositions to be taken by each party:

Joint Response: Ten fact depositions total per side, with a total limit of 70 hours of deposition time per side, in accordance with Fed. R. Civ. P. 30. Each Notice of Deposition under Fed. R. Civ. P. 30(b)(6) shall be counted as one fact deposition.

(e) Plaintiffs' expert report due on _____.

Joint Response: The parties' proposed schedule is attached hereto as Exhibit 1.

(f) Defendant's expert report due on _____.

Joint Response: The parties' proposed schedule is attached hereto as Exhibit 1.

(g) Motions to Amend or to Add Parties to be filed by _____.

Joint Response: The parties' proposed schedule is attached hereto as Exhibit 1.

(h) Dispositive motions to be served within ___30_____ days of completion of discovery.

Joint Response: The parties' proposed schedule is attached hereto as Exhibit 1.

(i) Factual discovery to be completed by _____.

Joint Response: The parties' proposed schedule is attached hereto as Exhibit 1.

(j) Expert discovery to be completed by _____.

Joint Response: The parties' proposed schedule is attached hereto as Exhibit 1.

(k) Set forth any special discovery mechanism or procedure requested, including data preservation orders or protective orders:

Joint Response: The parties will submit a proposed Discovery Confidentiality Order pursuant to Exhibit 1.

(l) A pretrial conference may take place on: _____.

Joint Response: The parties' proposed schedule is attached hereto as Exhibit 1.

(m) Trial by jury or non-jury Trial?

Joint Response: Non-Jury trial.

(n) Trial date: _____.

Joint Response: The parties' proposed schedule is attached hereto as Exhibit 1.

7. Do you anticipate any discovery problem(s)? Yes ___ No _X_. If so, explain.

8. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problem with out-of-state witnesses or documents, etc.)? Yes _____ No _X_.

Joint Response: At this point in time, due to the uncertainty of the ongoing COVID-19 pandemic, it is unclear whether there will be a need for special discovery. The parties, however, recognize that this matter may involve disruptions in discovery as a result of the COVID-19 pandemic. To the extent that the COVID-19 pandemic renders in person depositions impractical, the parties may conduct depositions via remote means, such as videoconferencing. To the extent that both an in-person and a remote deposition are impractical or impossible due to local restrictions, the parties will make good faith efforts to provide the witness in a location where such depositions are possible.

9. State whether this case is appropriate for voluntary arbitration (pursuant to L. Civ. R. 201.1 or otherwise), mediation (pursuant to L. Civ. R. 301.1 or otherwise), appointment of a special master or other special procedure. If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition of dispositive motions, etc.).

Joint Response: The parties agree that the case is not appropriate for voluntary arbitration, mediation, appointment of a special master, or other special procedure at this time.

10. Is this case appropriate for bifurcation? Yes ___ No _X_.

11. We do ____ do not _X_ consent to the trial being conducted by a Magistrate Judge.

12. Pursuant to Local Patent Rule 2.1(a), the parties report the following from the 26(f) conference:

(1) Proposed modification of the obligations or deadlines set forth in these Local Patent Rules to ensure that they are suitable for the circumstances of the particular case (see L. Pat. R. 1.3);

Joint Response: The parties have addressed this issue in the proposed schedule attached hereto as Exhibit 1.

(2) The scope and timing of any claim construction discovery including disclosure of and discovery from any expert witness permitted by the Court;

Joint Response: The parties have addressed this issue in the proposed schedule attached hereto as Exhibit 1.

(3) The format of the Claim Construction Hearing, including whether the Court will hear live testimony, the order of presentation, and the estimated length of the hearing;

Joint Response: The parties will submit this information in the Joint Claim Construction and Prehearing Statement on the date set forth in Exhibit 1.

(4) How the parties intend to educate the Court on the patent(s) at issue;

Joint Response: The parties intend to educate the Court on the patents at issue through at least submissions to the Court, which may include *Markman* tutorial(s).

(5) The need for any discovery confidentiality order and a schedule for presenting certification(s) required by L. Civ. R. 5.3(b)(2).

Joint Response: The parties will submit a proposed Discovery Confidentiality Order by the date set forth in Exhibit 1.

(6)

a. **The availability and timing of production of invention records (including inventor laboratory notebooks and analytical test results);**

Joint Response: Plaintiffs' investigation regarding the availability and timing of production of invention records is ongoing.

b. **The availability and timing of production of ANDA product research and development documents;**

Joint Response: In addition to Defendant's obligations pursuant to L. Pat. R. 3.6, the parties agree that to the extent ANDA product research and development documents are relevant to any party's claims or defenses and proportional to the needs of the case, and such materials are timely requested, Defendant will produce any non-privileged ANDA product research and development documents prior to the deadline of the substantial completion of document production set forth in Exhibit 1.

c. **The availability and timing of production of ANDA product samples;**

Joint Response: To the extent samples are relevant to any party's claims or defenses and proportional to the needs of the case, and such materials are timely requested, the parties will meet and confer regarding the production of ANDA product samples and, to the extent such production is made, the timing

will be prior to the deadline for the substantial completion of document production set forth in Exhibit 1.

d. **The date of conception and the date of reduction to practice for each patent asserted in the action, if applicable;**

Joint Response: Plaintiffs will provide the information required by the Local Patent Rules with their contentions.

e. **Each inventor's availability for deposition in the matter;**

Joint Response: The sole inventor of the '499 patent is Elliot Ehrich. At this time, Plaintiffs believe Mr. Ehrich will be available for deposition in this matter at a reasonable time and place. He may be contacted only through outside counsel for Plaintiffs in this matter.

f. **Availability of foreign witnesses for deposition and foreign documents;**

Joint Response: The parties are not aware at this time of foreign witnesses or foreign documents. To the extent that foreign witnesses or foreign documents are relevant, the parties will confer regarding the availability of foreign witnesses for deposition and production of foreign documents and work in good faith to resolve any disputes relating thereto.

g. **Whether there is a 30-month stay and if so, when it ends;**

Joint Response: January 31, 2023.

h. **A date for substantial completion of document production and a method for determining compliance;**

Joint Response: The parties' proposed schedule is attached hereto as Exhibit 1.

i. **Any other issues or matters that a party believes are time sensitive.**

Joint Response: None at this time.

Respectfully submitted,

Dated: February 3, 2021

s/ Charles M. Lizza
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EXHIBIT 1

Event	Tentative Date
Initial meeting of the parties	January 15, 2021 (Friday)
Proposed Joint Discovery Plan provided to the Magistrate Judge	February 3, 2021 (Wednesday)
Parties to exchange Initial Disclosures pursuant to Fed. R. Civ. P. 26(a)(1)(c)	January 29, 2021 (Friday)
Rule 16 Initial Scheduling Conference	February 5, 2021 at 2:30 PM (Friday)
Plaintiffs to serve "Disclosure of Asserted Claims" pursuant L. Pat. R. 3.6(b)	February 12, 2021 (Friday)
Parties to submit Proposed Discovery Confidentiality Order pursuant to L. Pat. R. 2.2	February 19, 2021 (Friday)
Defendant to serve "Invalidity Contentions" and "Non-infringement Contentions," and to produce underlying documents pursuant to L. Pat. R. 3.6(c)-(f)	March 8, 2021 (Monday)
Plaintiffs to serve "Responses to Invalidity Contentions" and "Disclosure of Infringement Contentions" and produce underlying documents pursuant to L. Pat. R. 3.6(g)-(i)	April 22, 2021 (Thursday)
Parties to exchange claim terms to be construed pursuant to L. Pat. R. 4.1(a)	May 6, 2021 (Thursday)
Parties to exchange "Preliminary Claim Constructions" and identification of supporting intrinsic and extrinsic evidence pursuant to L. Pat. R. 4.2(a)-(b)	May 27, 2021 (Thursday)
Parties to exchange identification of intrinsic and extrinsic evidence in support of opposition to other party's proposed constructions pursuant to L. Pat. R. 4.2(b) and (c)	June 10, 2021 (Thursday)

Event	Tentative Date
Parties to file Joint Claim Construction and Prehearing Statement pursuant to L. Pat. R. 4.3	June 28, 2021 (Monday)
Completion of fact discovery relating to claim construction, including depositions of non-expert witnesses identified in claim construction exchanges pursuant to L. Pat. R. 4.4	July 28, 2021 (Wednesday)
Parties to simultaneously file Opening *Markman* Briefs pursuant to L. Pat. R. 4.5(a)	August 12, 2021 (Thursday)
Completion of Expert Discovery Relating to Opening *Markman* Briefs pursuant to L. Pat. R. 4.5(b)	September 13, 2021 (Monday)
Parties to file Responsive *Markman* Briefs pursuant to L. Pat. R. 4.5(c)	October 12, 2021 (Tuesday)
Parties to submit proposed claim construction hearing schedule pursuant to L. Pat. R. 4.6	October 26, 2021 (Tuesday)
Markman Hearing	Subject to the Court's availability November 2021
Date for substantial completion of document production	October 13, 2021 (Wednesday)
Deadline for parties to seek leave to amend pleadings or join parties	November 4, 2021 (Thursday)
Close of fact discovery	December 16, 2021 (Thursday)
Parties to exchange Opening Expert reports on issues for which a party bears the burden of proof	January 13, 2022 (Thursday)
Parties to exchange Rebuttal Expert Reports (including Plaintiffs' opening positions on secondary considerations)	February 17, 2022 (Thursday)

Event	Tentative Date
Parties to exchange Reply Expert Reports (including Defendant's rebuttal positions on secondary considerations)	March 10, 2022 (Thursday)
Close of Expert Discovery	April 13, 2022 (Wednesday)
Deadline to File Dispositive Motions	May 13, 2022 (Friday)
Submission of Final Pretrial Order	May 25, 2022 (Wednesday)
Final Pretrial Conference	Late June 2022 or subject to the Court's availability
Trial	Late July 2022 or subject to the Court's availability